SPS/TBT NOTIFICATIONS
AFFECTING AGRICULTURAL TRADE

Listed below are proposed changes in international agricultural, food and related standards as notified via the World Trade Organization; The first table provides a **summary** of all notifications; **Individual details** follow separately. Interested parties may obtain a full text of any notification for review and COMMENT; simply circle the FSTSD# or otherwise indicate which items on the summary table and return by fax **(202) 690-0677** to the attention of Deborah A. Thompson, **F**ood **S**afety & **T**echnical **S**ervices **D**ivision in USDA/FAS.

Also, if applicable, please provide us with your **E-mail address** {on the request form}. Currently we are receiving some full texts electronically. If you have questions regarding a technical matter, call Carolyn Fillmore Wilson at (202) 720-2239. **Please call Ms. Thompson at (202) 720-9124 for address/telephone changes**.

NOTE: *Please include your name/fax number on all request forms.*

Type	WTO#	Product Covered	Country	FSTSD#
TBT	00.0609	Formulated Caffeinated Beverages...	Australia	00.0103
SPS	N/BGR/3/Rev.1	Bovine Animals & Related Products	Bulgaria	00.0367.R01
SPS	N/EEC/108	Feedingstuffs	European Union	00.0391
SPS	N/EEC/109	Live Bovine and Porcine Animals	European Union	00.0392
TBT	00.0591	Foods with Health Claims	Japan	00.0101
TBT	00.0600	Fertilizer	Japan	00.0102
SPS	N/KOR/76	Non-human primates	Korea, Republic of	00.0385
SPS	N/PHL/25	European Live Animals& Products	Philippines	00.0393
SPS	N/POL/24	BovineAnimals,Beef,Beef Products...	Poland	00.0394
SPS	N/USA/366	Ruminants and swine	United States of America	00.0386
SPS	N/USA/367	Veterinary Medicinal Products	United States of America	00.0387
SPS	N/USA/368	Veterinary Medicinal Products	United States of America	00.0388
SPS	N/USA/369	Veterinary Medicinal Products	United States of America	00.0389
SPS	N/USA/370	Veterinary Medicinal Products	United States of America	00.0390
SPS	N/USA/371	Pesticides	United States of America	00.0395
SPS	N/USA/372	Pesticides	United States of America	00.0396
SPS	N/USA/373	Pesticides	United States of America	00.0397

USDA/FAS/FSTSD No. **00.0367.R01** **Bulgaria** **Bovine Animals & Related Products**

Comment Deadline Date: *Enforcement Date:* **12/15/00** *WTO Type & #:* **SPS N/BGR/3/Rev.1**

Objective: Food Safety, Animal Health, Protect humans from animal/plant pest or disease

EMERGENCY MESAURE: Nature of the urgent problem(s): Bovine Spongiform Encephalopathy (BSE)-related measure.

Description of content: Import ban for bovine animals, meat and meat products, animal feed and meals, immunological products and other products specified below:

- Live bovine animals, meat, meat products, offals, semen, embryos and ova from bovine animals; meals, bio concentrates and feed for carnivores, when containing protein derived from ruminant animals from the United Kingdom of Great Britain and Northern Ireland, the Republic of Ireland, Switzerland, Belgium, Portugal and France;
- Live bovine animals; meat, meat products, offals, semen, embryos and ova from bovine animals; meals, bio concentrates and feed for carnivores, when containing protein derived from ruminant animals from the Netherlands, Denmark, Spain and Germany, excluding deboned carcass meat, derived from bovine animals of age under 18 months, originating from areas within these countries in which no cases of Bovine Spongiform Encephalopathy have been detected;
- Immunological products, vaccine, hormonal products, bio stimulators, allergens, cosmetics products and other preparates prepared from organs of ruminant animals originating from the United Kingdom of Great Britain and Northern Ireland, the Republic of Ireland, Switzerland, Belgium, Portugal and France and areas within the Netherlands, Denmark, Spain and Germany, in which cases of Bovine Spongiform Encephalopathy have been confirmed.

USDA/FAS/FSTSD No. **00.0385** **Korea, Republic of** **Non-human primates**

Comment Deadline Date: **2/28/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/KOR/76**

Objective: Animal Health, Protect humans from animal/plant pest or disease

Description of content: In order to prevent the introduction of non-human primates infected with Ebola or Marburg virus into the Republic of Korea, the non-human primates shall be imported in accordance with the import quarantine procedures based on the OIE guideline from the regions where Ebola or Marburg diseases do not occur.

USDA/FAS/FSTSD No. **00.0386** **United States of America** **Ruminants and swine**

Comment Deadline Date: *Enforcement Date:* **10/01/00** *WTO Type & #:* **SPS N/USA/366**

Objective: Animal Health

EMERGENCY MEASURE: Nature of the urgent problem(s): This action is necessary to prevent the introduction of foot-and-mouth disease into the United States.

Description of content: APHIS is amending the regulations governing the importation of certain animals, meat, and other animal products by removing Artigas, a department in Uruguay, from the list of regions considered to be free of rinderpest and foot-and-mouth disease. We are taking this action because the existence of foot-and-mouth disease has been confirmed there. The effect of this action is to prohibit or restrict the importation of any ruminant or swine and any fresh (chilled or frozen) meat and other products of ruminants or swine into the United States from Artigas. APHIS invites your comments and will consider all comments received by February 12, 2001.

USDA/FAS/FSTSD No. **00.0387** **United States of America** **Veterinary Medicinal Products**

Comment Deadline Date: **1/17/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/367**

Objective: Food Safety, Animal Health

Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance document for industry (No. 116) entitled ``Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23). This draft guidance document has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the genotoxicity of veterinary drug residues in human food in the European Union, Japan, and the United States.

USDA/FAS/FSTSD No. **00.0388** **United States of America** **Veterinary Medicinal Products**

Comment Deadline Date: **1/17/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/368**

Objective: Animal Health

Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#117) entitled ``Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMP's) submitted to the European Union, Japan, and the United States.

USDA/FAS/FSTSD No. **00.0389** **United States of America** **Veterinary Medicinal Products**

Comment Deadline Date: **1/17/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/369**

Objective: Animal Health

Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of two draft guidances for industry (Nos. 113 and 114, respectively) entitled ``Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ``Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

USDA/FAS/FSTSD No. **00.0390** **United States of America** **Veterinary Medicinal Products**

Comment Deadline Date: **2/20/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/370**

Objective: Food Safety, Animal Health

Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#115) entitled ``Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies'' (VICH GL22). This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food. This draft guidance is intended to provide harmonized guidance on the core recommendation for a multigeneration study for the safety evaluation of veterinary drug residues in human food. The current draft guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on ``Detection of Toxicity to Reproduction for Medicinal Products'' and its addendum, ``Toxicity to Male Fertility,'' in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

USDA/FAS/FSTSD No. **00.0391** **European Union** **Feedingstuffs**

Comment Deadline Date: *Enforcement Date:* **01/01/01** *WTO Type & #:* **SPS N/EEC/108**

Objective: Food Safety, Animal Health, Protect humans from animal/plant pest or disease

EMERGENCY MEASURE: Nature of the urgent problem(s): EC inspections have identified failures in the implementation of feedingstuffs rules in several member States, and certain member States, next to the discovering of deficiencies of similar nature have adopted safeguard measures in line with the recommendation of the Scientific Steering Committee (SSC) that "where the risk of cross-contamination of cattle feed with feed destined to other animals cannot be excluded, a temporary ban of animal proteins in animal feed should be considered".

Description of content: This Decision establishes, as a precautionary measure, a temporary prohibition (1 January 2001-30 June 2001) of the feeding to farmed animals (which are kept, fattened or bred for the production of food), placing on the market, trade, imports from third countries, and exportation to third countries of the following products: processed animal proteins such as meat-and-bone meal, meat meal, bone meal, blood meal, dried plasma and other blood products, hydrolysed proteins, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatine and any other similar products including mixtures, feedingstuffs, feed additives and premixtures, containing these products. The exceptions (i) fishmeal fed to animals other than ruminants, (ii) gelatine of non-ruminants origin for coating feedingstuffs additives (iii) dicalcium phosphate and hydrolysed proteins obtained in accordance with certain conditions and (iv) milk and milk products. During this period, all processed animal proteins will be withdrawn from the market, distribution channels and from on-farm storage and all animal waste will be collected, transported, processed, stored and disposed of in a safe manner. Processed animal protein may be used in feed for pets, fur animals and other non-food species.

USDA/FAS/FSTSD No. **00.0392** **European Union** **Live Bovine and Porcine Animals**

Comment Deadline Date: **3/1/2001** *Enforcement Date:* **07/01/01** *WTO Type & #:* **SPS N/EEC/109**

Objective: Animal Health

Description of content: This proposal aims to clarify and simplify the EC legislation by updating a significant number of legislative acts concerning the animal health conditions required for imports of domestic bovine and porcine animals from the third countries (or part of their territories) and repeals numerous Commission decisions.

USDA/FAS/FSTSD No. **00.0393** **Philippines** **European Live Animals& Products**

Comment Deadline Date: **12/29/2000** *Enforcement Date:* **11/29/00** *WTO Type & #:* **SPS N/PHL/25**

Objective: Food Safety, Animal Health, Protect humans from animal/plant pest or disease

EMERGENCY MEASURE: Nature of the urgent problem(s): Increasing cases of Bovine Spongiform Encephalopathy (BSE) or Mad Cow Disease in the European Countries.

Description of content: Temporary ban on the importation of live cattle, sheep, goats and their meat and meat products; bovine embryo; meat and bone-meal and other feed ingredients derived from the said animals in view of the increasing cases of Bovine Spongiform Encephalopathy (BSE) or Mad Cow Disease in European countries.

USDA/FAS/FSTSD No. **00.0394** **Poland** **BovineAnimals,Beef,Beef Products...**

Comment Deadline Date: *Enforcement Date:* *WTO Type & #:* **SPS N/POL/24**

Objective: Food Safety, Animal Health, Protect humans from animal/plant pest or disease

EMERGENCY MEASURE: Nature of the urgent problem(s): Bovine Spongiform Encephalopathy detected and confirmed in countries-France, Belgium, Netherlands, Spain, Denmark, Germany, Luxembourg, Liechtenstein, Portugal, United Kingdom, Switzerland and Ireland

Description of content: Import ban for commodities listed in an Annex to the Regulation.

USDA/FAS/FSTSD No. **00.0395** **United States of America** **Pesticides**

Comment Deadline Date: **2/20/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/371**

Objective: Food Safety

Description of content: EPA is announcing the availability of the Reregistration Eligibility Decision (RED) documents for the pesticide active ingredients diclofop-methyl, etridiazole (Terrazole), and vinclozolin. The REDs represent EPA's formal regulatory assessments of the health and environmental data bases of the subject chemicals and present the Agency's determination regarding which pesticidal uses are eligible for reregistration.

USDA/FAS/FSTSD No. **00.0396** **United States of America** **Pesticides**

Comment Deadline Date: **1/19/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/372**

Objective: Food Safety

Description of content: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

EPA has received a pesticide petition proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for octanal when used as an inert ingredient in the pesticide formulations applied to growing crops or to raw agricultural commodities (RACs) after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001(e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

EPA has received a pesticide petition to establish an exemption from the requirement of a tolerance for ethyl maltol when used as an inert ingredient in the pesticide formulations applied to growing crops or to RAC after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001 (e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

EPA has received a pesticide petition, to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for ethyl methylphenylglycidate when used as an inert ingredient in the pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001 (e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

USDA/FAS/FSTSD No. **00.0397** **United States of America** **Pesticides**

Comment Deadline Date: **1/19/2001** *Enforcement Date:* *WTO Type & #:* **SPS N/USA/373**

Objective: Food Safety

Description of content: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

EPA has received a pesticide petition proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and (e), to establish an exemption from the requirement of a tolerance for polybutylene as an inert ingredient in or on growing crops or when applied to the raw agricultural commodity (RAC) after harvest or when applied to animals. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

USDA/FAS/FSTSD No. **00.0101** **Japan** **Foods with Health Claims**

Comment Deadline Date: **2/9/2001** *Enforcement Date:* **04/01/01** *WTO Type & #:* **TBT 00.0591**

Objective: Protection of public health

Description of content: Outline of the planned amendments regarding foods intended to declare the effect on structure/function of the human body are as follows:

(1) Setting two types of classification of foods allowed to be labelled health claims;
- Types of foods that should be evaluated individually (Type 1); and
- Types of foods for which standard regulation is applied (Type 2).

(2) Setting standards for food labelling concerning attention, warning and other related matters;

(3) Setting guidelines for the application, evaluation and related matters of foods that should be evaluated individually (Type 1).

USDA/FAS/FSTSD No. **00.0102** **Japan** **Fertilizer**

Comment Deadline Date: **2/19/2001** *Enforcement Date:* **04/00/01** *WTO Type & #:* **TBT 00.0600**

Objective: Upon request from manufacturers of fertilizer etc., establish or amend official specification for fertilizers, extend the effective period o registration regarding part of the fertilizer.

Description of content:

1. Establish the Standards for the following substances:
   - Glycoluril;
   - Methylene ureas fertilizer
   - Fused silicate phosphate (Fused mixture o silicate and phosphate rock)
   - Compound fertilizer incorporated with agricultural chemicals for home gardens;
2. Amend the Standards for the following substances:
   - Complex fertilizer incorporated with agricultural chemicals;
   - Part of the Complex fertilizer;
   - Part of the Mixed fertilizer.

USDA/FAS/FSTSD No. **00.0103** **Australia** **Formulated Caffeinated Beverages...**

Comment Deadline Date: **2/23/2001** *Enforcement Date:* *WTO Type & #:* **TBT 00.0609**

Objective: The application under consideration is primarily health related and is concerned with the protection of human health and safety. It includes certain labelling requirements. This will have the effect of removing a trade barrier in Australia due to a prohibition of the manufacture and import of energy drinks.

Description of content: This application is to introduce a new standard to the Australian Food Standards Code and the Australia New Zealand Food Standards Code-in order to enable manufacture and direct import of formulated caffeinated beverages in Australia. The application will include permission for specific substances, including certain B complex vitamins, caffeine and substances such as taurine, glucuronolactone and inositol to be added to non-alcoholic water based beverages, subject to maximum levels. Application contains certain labelling requirements.

End of this report.